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10/825,309	04/16/2004	Richard S. Kuslcika	12013/48803	7747
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KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			VU, QUYNH-NHU HOANG	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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*In re* Application of:  
KUSLEIKA, RICHARD S.  
Serial No.: 10/825,309 : DECISION ON PETITION  
Filed: April 16, 2004 : under 37 CFR 1.181  
Docket: 12013/48803  
Title: CATHETER FOR TISSUE DILATION  
AND DRUG DELIVERY

This is a decision on the petition filed on March 22, 2010 filed under 37 CFR 1.181 seeking to have the ground of the rejection in the Examiner's Answer mailed on January 22, 2010 be designated as a new ground of rejection. The petition is being considered pursuant to 37 CFR 1.181 and no fee is required.

The petition is dismissed.

The following relevant facts include:

1. On March 5, 2009, the examiner issued a final rejection. In the final rejection, claims 16-24, 38-39 are rejected under 35 U.S.C. 103(a) as obvious over Shockey et al. (US 4,994,033) in view of Sogard et al. (US 5,447,497). The examiner explained what the primary reference teaches. In particular, the examiner also explained that Sogard discloses a similarly device comprising an elongate flexible catheter 20 having a flexible treatment sheath (outer sheath) 26 mounted to a distal end region of the catheter and a dilatation balloon (inner balloon) 28 within the flexible treatment sheath 26, wherein the flexible treatment sheath 26 is formed of an elastic member, such as high-compliant balloon are made from soft or flexible polymeric materials and the dilatation/inner balloon 28 is non-compliant balloon are made from inelastic materials such as rigid or stiff polymeric materials. The examiner emphasized that Applicant acknowledged that the inelastic materials such as PET, polypropylene on page 2 of Pre-Appeal Brief filed 7/28/08) are similar to materials that Sogard discussed in col. 2, lines 43-52, col. 8, lines 49-50. In conclusion of the rejection of the claims, the examiner stated that it would have

been obvious to a person skilled in the art "to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard, in order to dilate and prevent the rupture of balloon since the small increase in diameter when the balloon inflated to its expanded diameter".

2. On May 28, 2009, the applicant filed a Pre-Appeal Brief Conference Request. One of the issues raised, *inter alia*, was the outer treatment sheath is "elastic" and the balloon is "substantially inelastic" so that the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.

3. On September 2, 2009, the decision on the Pre-Appeal Conference Request was mailed. The applicant was notified that the final rejection remains.

4. In response to the November 5, 2009 Notification of Non-compliant Appeal Brief, on December 2, 2009, the applicant filed a Supplemental Appeal Brief appealing the finally rejected claims 16-24 and 38-39. In the Brief, the Appellant argues, *inter alia*, that Shockey does not disclose the step of "while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site [and] cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue." The Appellant also argues that the examiner failed to explain why a person of ordinary skill in the art would choose an "elastic" material for the outer sleeve of Shockey.

5. In response to the Supplemental Appeal Brief, the examiner issued an Examiner's Answer. In the Examiner Answer, claims 16-24, 38-39 are rejected under 35 U.S.C. 103(a) as obvious over Shockey et al. (US 4,994,033) in view of Sogard et al. (US 5,447,497). The rejection of the claims is in verbatim as the final rejection of the claims. However, on page 5 of the Examiner's Answer, under the Section "Response to Arguments", in order to prove that the polyethylene tetrathalate or poly chloride material used in Sogard patent is "elastic". In accordance with the MPEP § 2131.01, the examiner cited two prior art patents Rey (US Pat. 5,413,822) and Woodyard (US Pat. 3,651,591) to support the material used in Sogard patent is "elastic" same as claimed.

6. On March 22, 2010, the appellant filed a Reply Brief with Attachment, *inter alia*, in response to the newly cited prior art references in the Examiner's Answer, the appellant also cited two rebuttal prior art references, namely, U.S. Patent 5,800,540 to Chin and U.S. Patent 5,474,563 to Myler showing the polyethylene, polyethylene terephthalate (PET), polyvinyl chloride [PVC], or other generally inelastic materials. Similarly, U.S. Patent No. 5,474,563 to Myler et al. states that a conventional balloon material may be used. The modulus of elasticity of both PET and PVC evidences that they are both substantially inelastic. Additionally, the appellant also cited a website of Material Properties, [www.plasticsintl.com](http://www.plasticsintl.com), listing the tensile modulus of PET as 400,000 psi and of PVC as 411,000 psi.

7. On March 22, 2010, the current petition was filed arguing that the examiner has improperly introduced a new ground of rejection in the Examiner's Answer of January 22, 2010. The applicant is requesting the rejection of claims of the Examiner's Answer to be designated as new ground of rejection. In the petition, petitioner argues that the citation of two new prior art references to Rey (US Pat. 5,413,822) and Woodyard (US Pat. 3,651,591) to prove the material used in the secondary prior art reference to Sogard patent is "elastic". Therefore, the rejection of claims must be designated as a new ground of rejection.

#### Discussion and Analysis

A review of the final rejection of March 5, 2009 and the Examiner's Answer of January 22, 2010 shows there is no new ground of rejection at all. The rejection of claims was never changed. In the petition, petitioner argues that the examiner's rebuttal arguments cited two new prior art references, Rey (US Pat. 5,413,822) and Woodyard (US Pat. 3,651,591), showing the material used in the secondary prior art reference to Sogard patent is "elastic". Therefore, the rejection of claims constitutes a new ground of rejection.

A careful study of the final rejection of March 5, 2009 and the Examiner Answer of January 22, 2010 does show that the rejection of claims was based on the teaching of flexible treatment sheath from Sogard patent. The appellant disagreed with the examiner. The examiner merely cited two prior art references to show such material used in the secondary reference as "elastic" under MPEP § 2131.01. The Examiner's Answer of January 22, 2010 simply does not show any new grounds of rejection. Petitioner also fails to identify any particular rejection under Paragraph 9 of the Examiner's Answer constitutes new ground of rejection. It should be noted that there is no new ground of rejection when the basic thrust of the rejection remains the same such that an appellant has been given a fair opportunity to react to the rejection. It is further noted in the Reply Brief of March 22, 2010, in order to negate what the examiner's interpretation of the "elastic" material is in the Sogard patent, the appellant was allowed to enter his new rebuttal prior art references, namely, U.S. Patent 5,800,540 to Chin and U.S. Patent 5,474,563 to Myler to show the material used in Sogard patent is not elastic. The applicant has fully rebutted the examiner's rebuttal arguments in the Examiner's Answer of January 22, 2010. In the letter of May 11, 2010, the examiner has considered the newly cited rebuttal prior art references by the appellant and permitted the entry of the Reply Brief for appeal purpose. Under the circumstances, the appellant had full opportunity to argue and react to the alleged new grounds of rejection.

The examiner's rebuttal arguments by citing two prior art references to show the material used in the secondary reference to Sogard patent in the Examiner's Answer do not alter the grounds of rejection presented in Section 9 of the Examiner's Answer. In this case, the statutory basis for the rejection and the evidence relied upon in support of the rejection remained the same in the final rejection and the Examiner's Answer. In such a circumstance, a change in the discussion of, or rationale in support of, a change of arguments, if any, the examiner's rebuttal arguments do not necessarily constitute a new

ground of rejection. See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425,426-27 (CCPA 1976); MPEP § 1207.03III)<sup>1</sup>. Petitioner should also note that even if the suggestion to characterize the examiner's rebuttal arguments in the Examiner's Answer of January 22, 2010 as new ground of rejection were persuasive, which it is not, the appellant still would have had a fair opportunity to react to these rebuttal arguments in the Reply Brief as permitted under 37 CFR 41.41(a) (1). In this case, the appellant in fact did file a Reply Brief and Attachment to react to the examiner's rebuttal arguments in the Examiner's Answer. A fair opportunity to react to the examiner's rebuttal arguments was already provided.

### Conclusion

For the foregoing reasons, the relief requested by petitioner will not be granted. Specifically, the requested designation of the rejection of claims as new ground of rejection in the Examiner's Answer of January 22, 2010 can not be granted. The Reply Brief with Attachment filed on May 11, 2010 was considered and entered by the examiner. In accordance with the Administrative Remand of June 2, 2010, the case is now being sent to the Board of Appeals and Interference for docketing.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision, 37 CFR 1.181(f). No extension of time under 37 CFR 1.136(a) is permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.181."

Any inquiry regarding this decision should be directed to Henry Yuen, Special Program Examiner, at (571) 272-4856.

The petition is dismissed.



Donald T. Hajec, Director  
Technology Center 3700

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<sup>1</sup> MPEP 1207.03 III states in pertinent part: There is no new ground of rejection when the basic thrust of the rejection remains the same such that an appellant has been given a fair opportunity to react to the rejection. See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976). Where the statutory basis for the rejection remains the same, and the evidence relied upon in support of the rejection remains the same, a change in the discussion of, or rationale in support of, the rejection does not necessarily constitute a new ground of rejection. Id. at 1303, 190 USPQ at 427 (reliance upon fewer references in affirming a rejection under 35 U.S.C. 103 does not constitute a new ground of rejection).